Figure 1
1/10

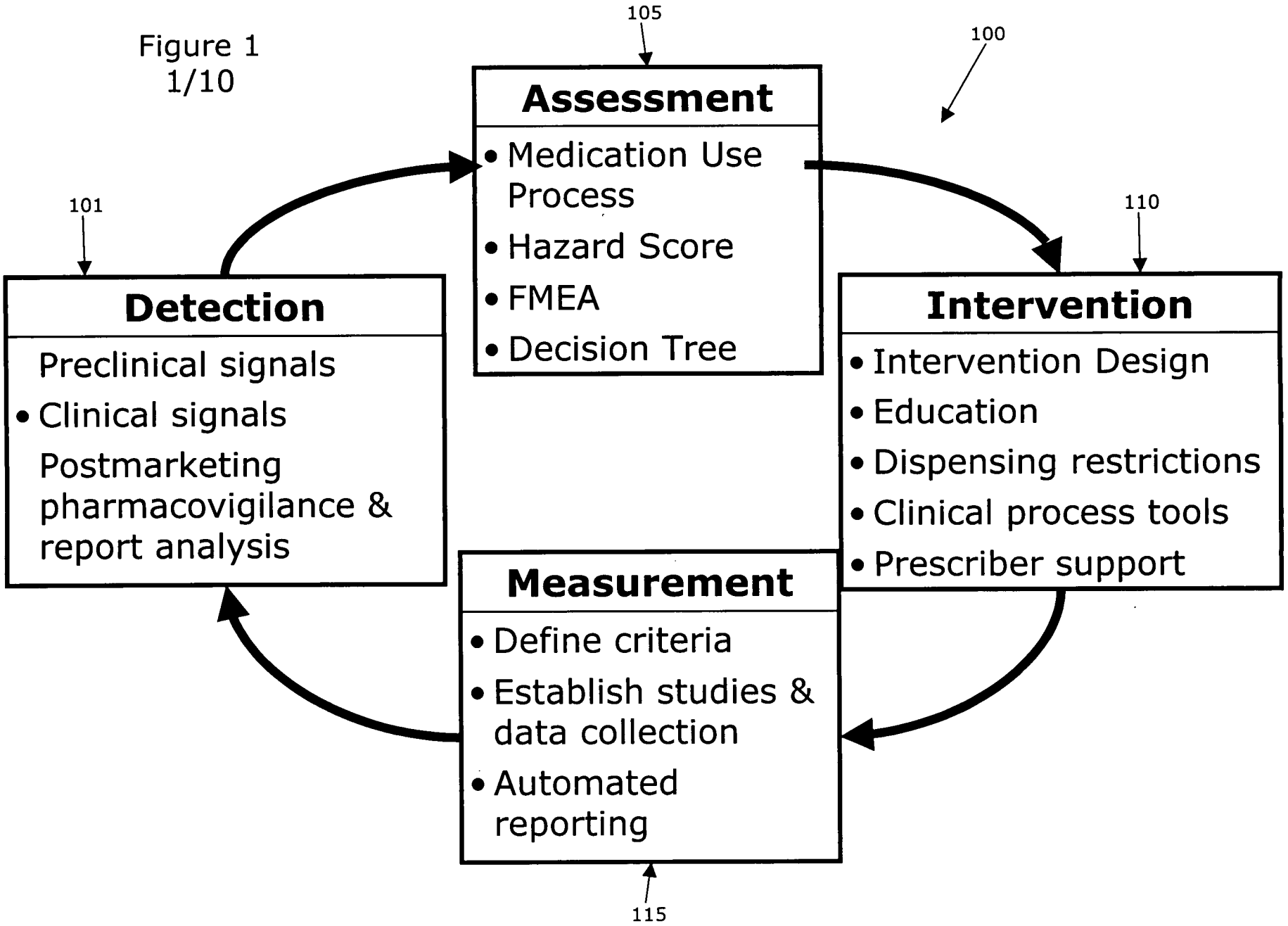
105
100
Assessment
• Medication Use Process
• Hazard Score
• FMEA
• Decision Tree
101
110
Detection
Preclinical signals
• Clinical signals
Postmarketing pharmacovigilance & report analysis
Intervention
• Intervention Design
• Education
• Dispensing restrictions
• Clinical process tools
• Prescriber support
Measurement
• Define criteria
• Establish studies & data collection
• Automated reporting
115

Figure 2
2/10

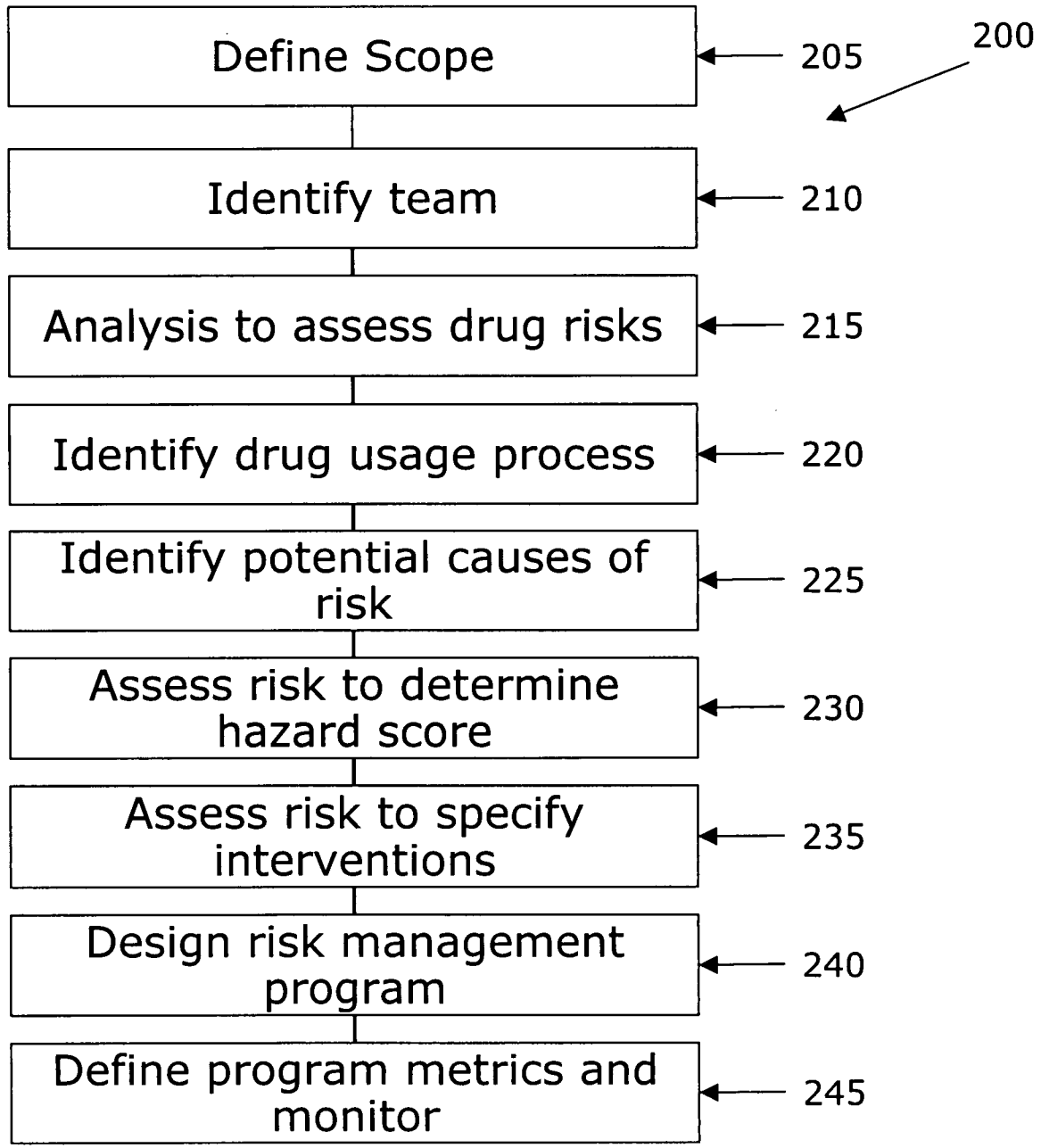
Define Scope
205
200
Identify team
210
Analysis to assess drug risks
215
Identify drug usage process
220
Identify potential causes of risk
225
Assess risk to determine hazard score
230
Assess risk to specify interventions
235
Design risk management program
240
Define program metrics and monitor
245

Figure 3
3/10

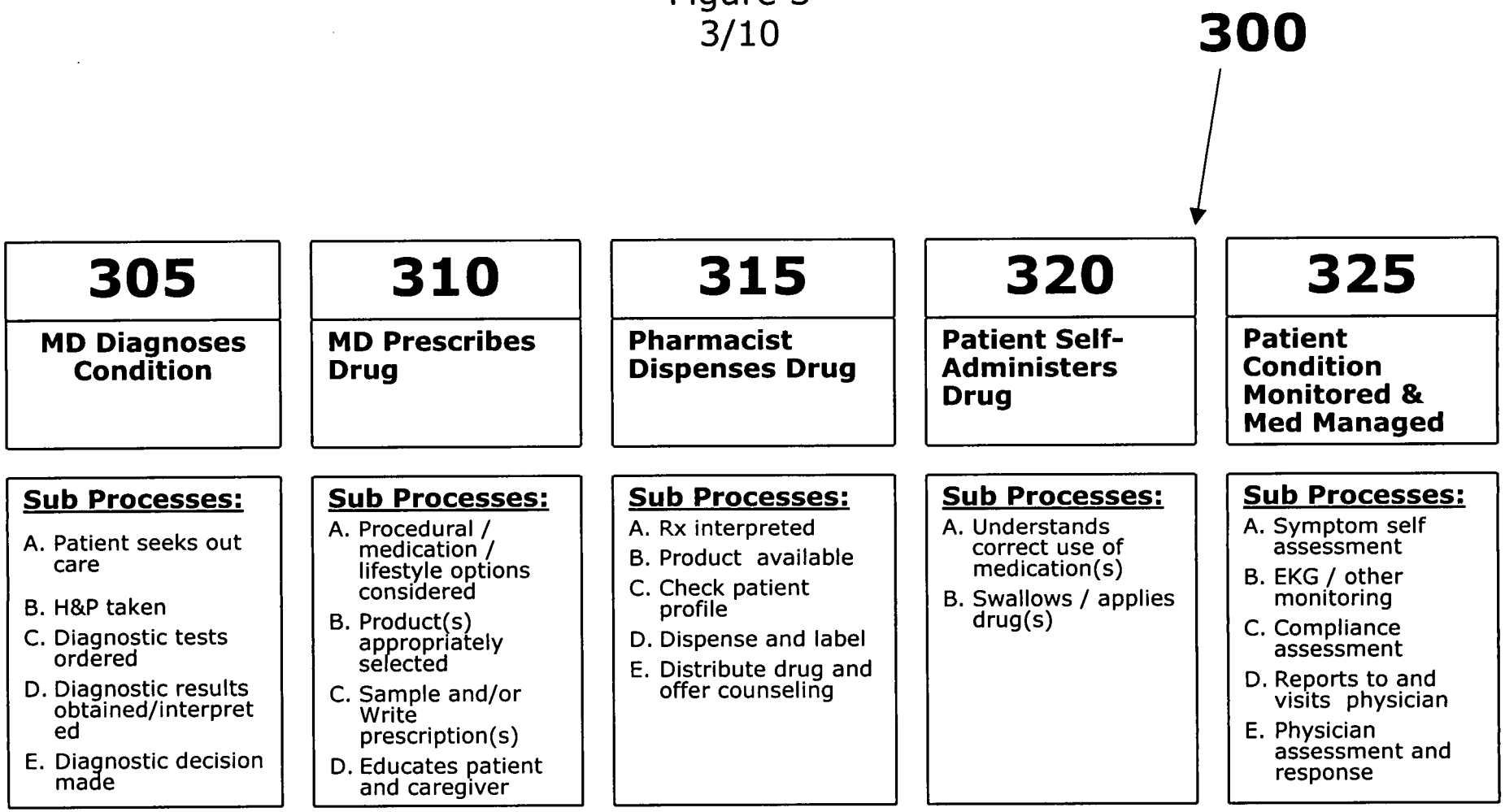
300
305
MD Diagnoses Condition
Sub Processes:
A. Patient seeks out care
B. H&P taken
C. Diagnostic tests ordered
D. Diagnostic results obtained/interpreted
E. Diagnostic decision made
310
MD Prescribes Drug
Sub Processes:
A. Procedural / medication / lifestyle options considered
B. Product(s) appropriately selected
C. Sample and/or Write prescription(s)
D. Educates patient and caregiver
315
Pharmacist Dispenses Drug
Sub Processes:
A. Rx interpreted
B. Product available
C. Check patient profile
D. Dispense and label
E. Distribute drug and offer counseling
320
Patient Self-Administers Drug
Sub Processes:
A. Understands correct use of medication(s)
B. Swallows / applies drug(s)
325
Patient Condition Monitored & Med Managed
Sub Processes:
A. Symptom self assessment
B. EKG / other monitoring
C. Compliance assessment
D. Reports to and visits physician
E. Physician assessment and response

Figure 4
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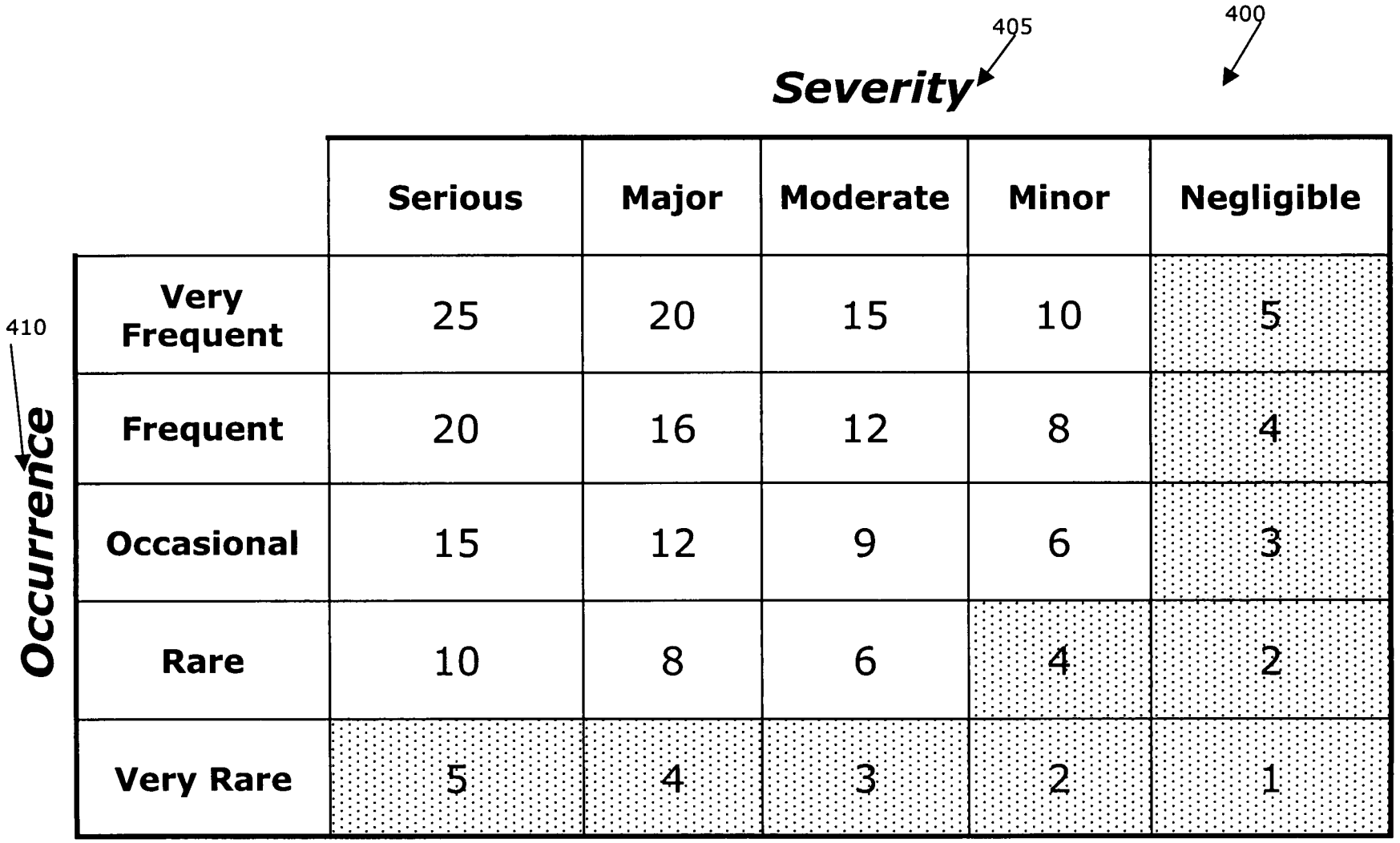
405
400
Severity
410
Occurrence
Serious
Major
Moderate
Minor
Negligible
Very Frequent
25
20
15
10
5
Frequent
20
16
12
8
4
Occasional
15
12
9
6
3
Rare
10
8
6
4
2
Very Rare
5
4
3
2
1

Figure 5
5/10

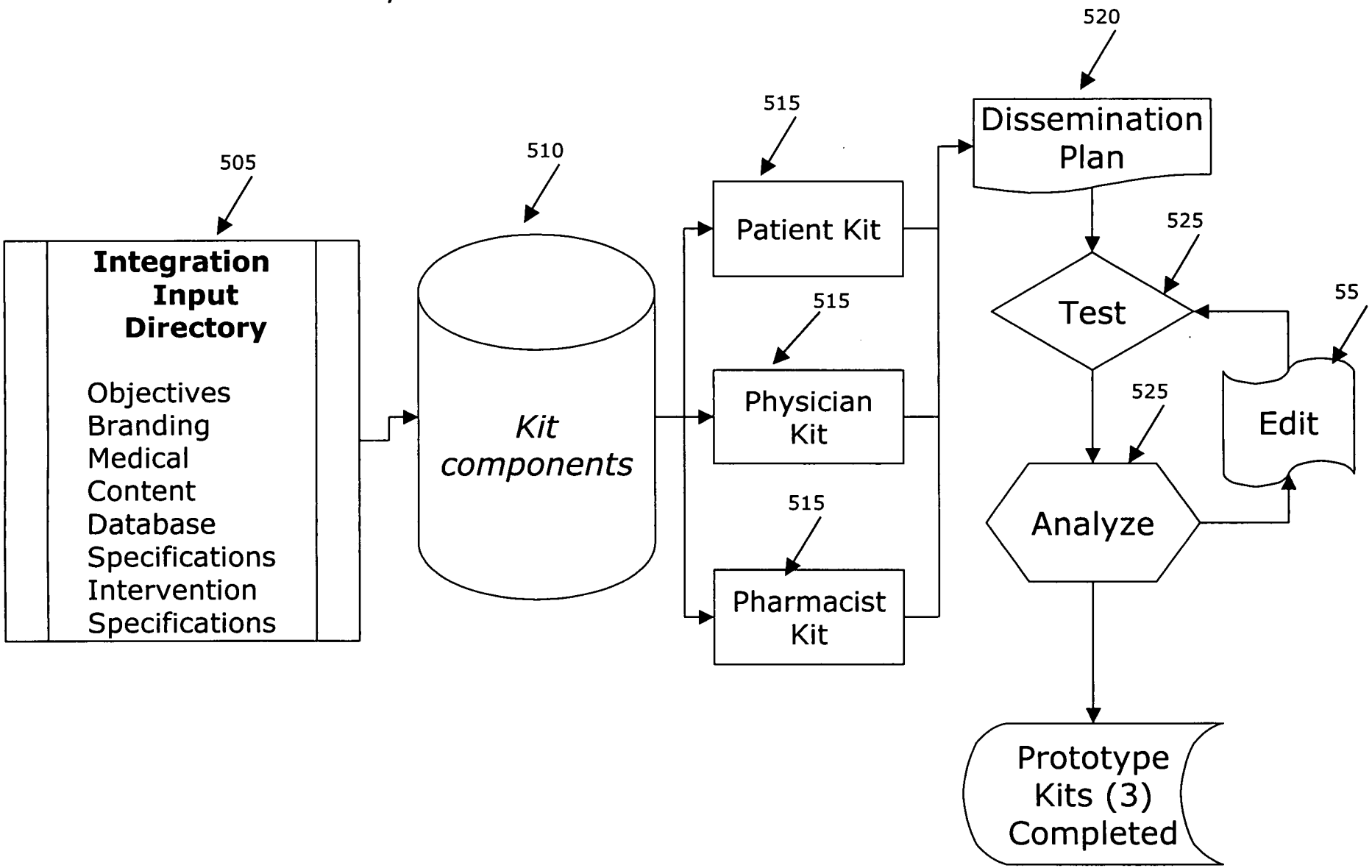
505
Integration Input Directory
Objectives
Branding
Medical Content
Database Specifications
Intervention Specifications
510
Kit components
515
Patient Kit
515
Physician Kit
515
Pharmacist Kit
520
Dissemination Plan
525
Test
525
Analyze
55
Edit
Prototype Kits (3) Completed

Figure 6
6/10

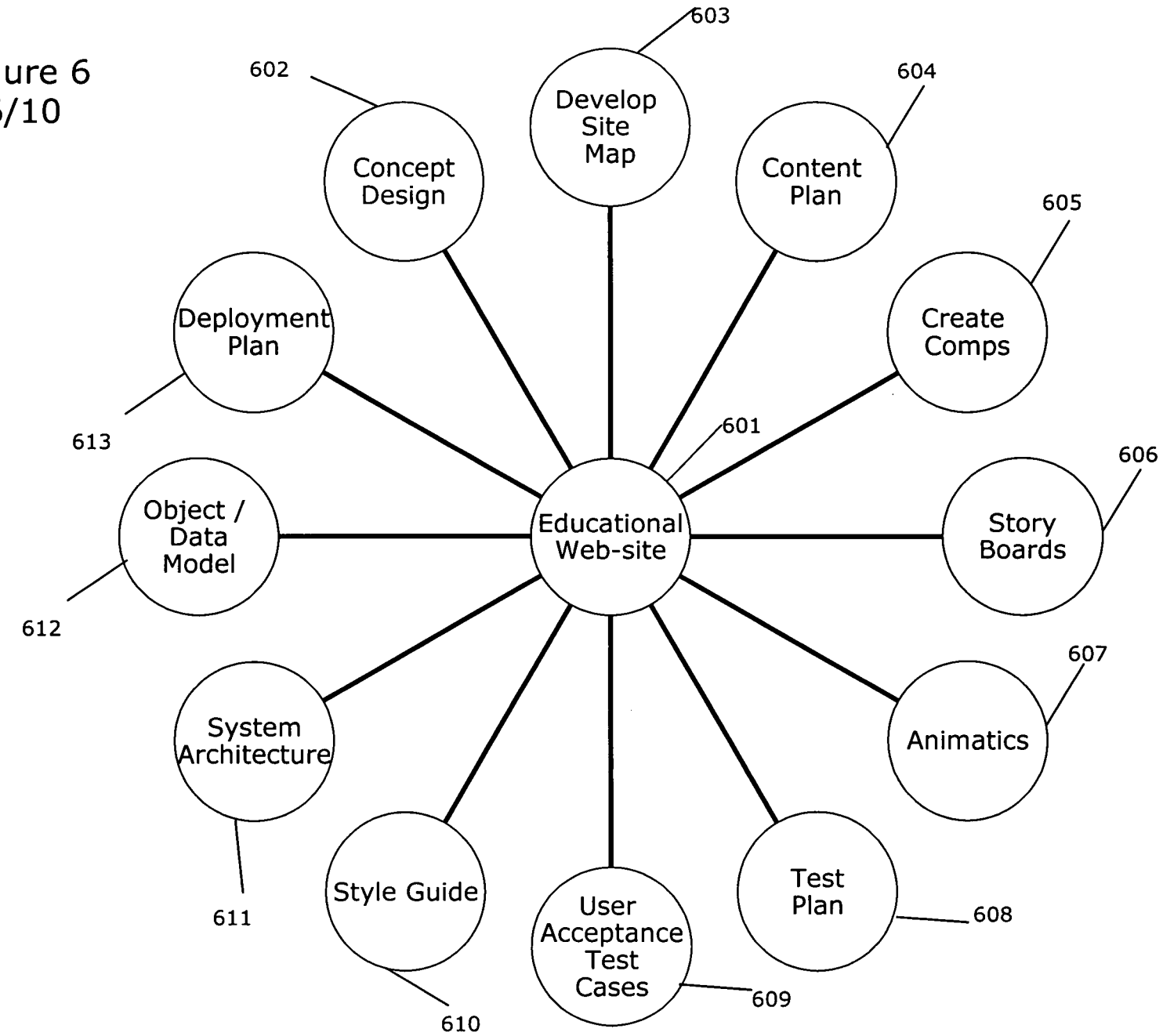
Educational Web-site
601
Concept Design
602
Develop Site Map
603
Content Plan
604
Create Comps
605
Story Boards
606
Animatics
607
Test Plan
608
User Acceptance Test Cases
609
Style Guide
610
System Architecture
611
Object / Data Model
612
Deployment Plan
613

Figure 7
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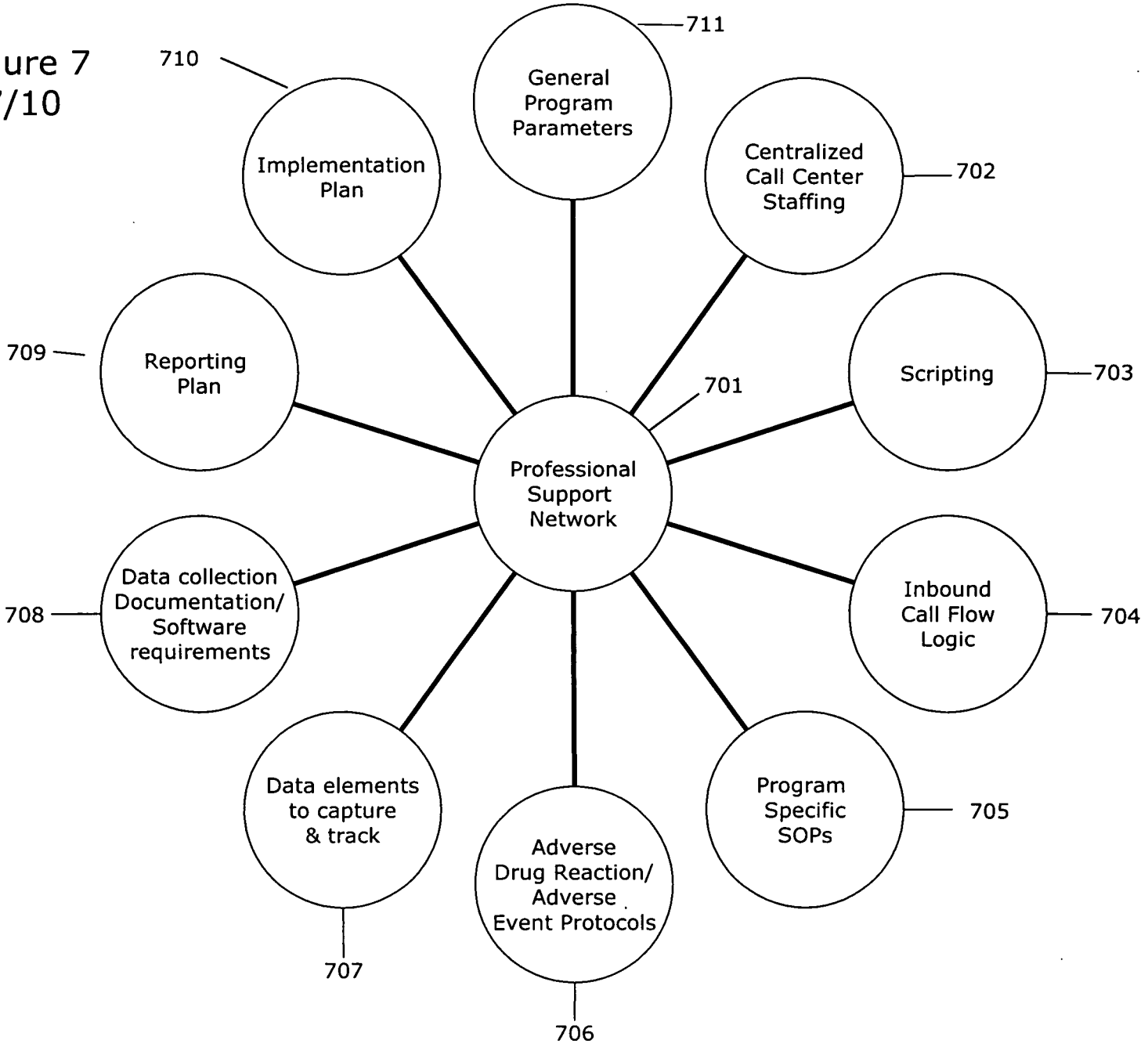
Professional Support Network
701
General Program Parameters
711
Centralized Call Center Staffing
702
Scripting
703
Inbound Call Flow Logic
704
Program Specific SOPs
705
Adverse Drug Reaction/ Adverse Event Protocols
706
Data elements to capture & track
707
Data collection Documentation/ Software requirements
708
Reporting Plan
709
Implementation Plan
710

Figure 8
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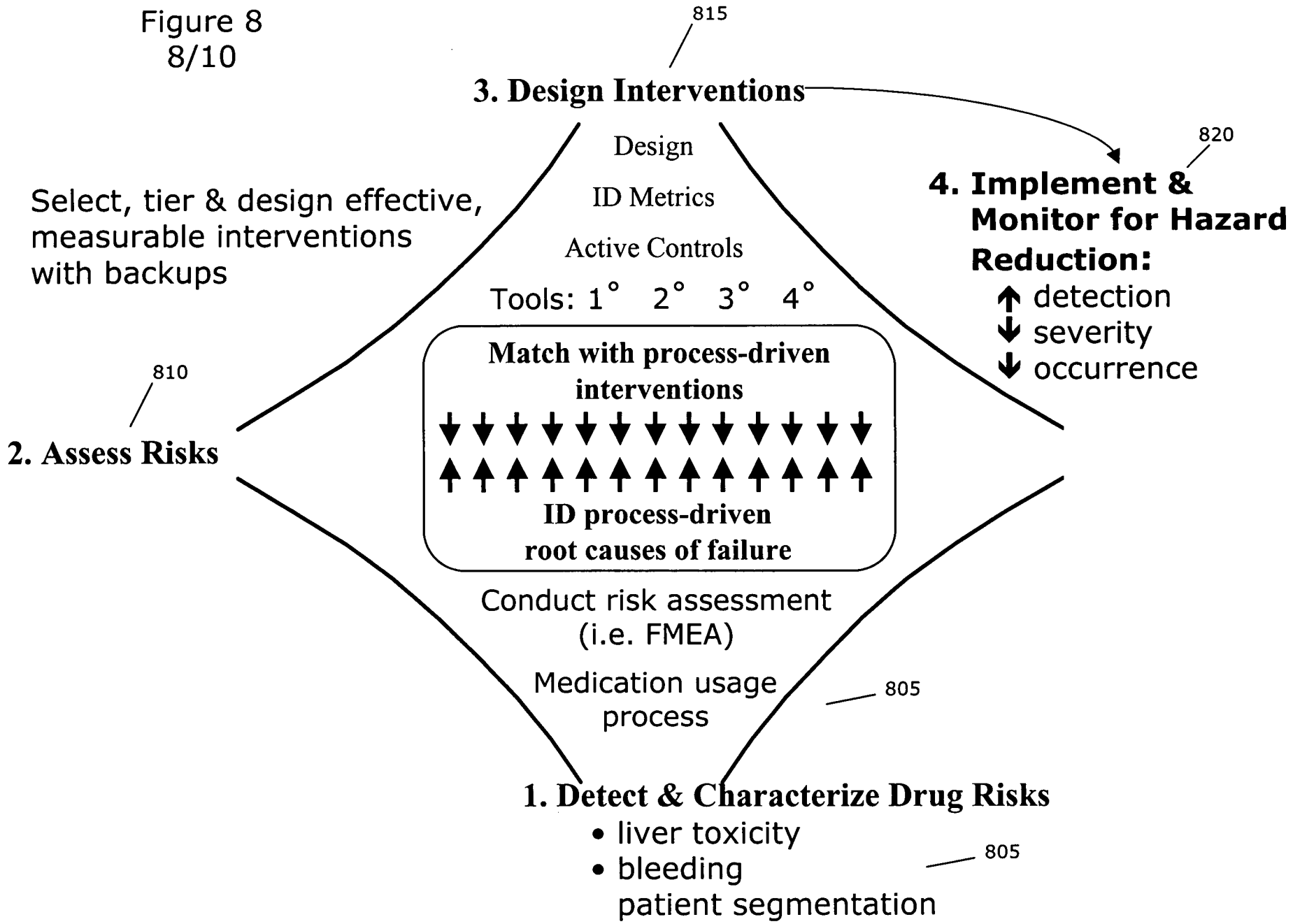
815
3. Design Interventions
820
4. Implement & Monitor for Hazard Reduction:
detection
severity
occurrence
Select, tier & design effective, measurable interventions with backups
Design
ID Metrics
Active Controls
Tools: 1° 2° 3° 4°
Match with process-driven interventions
ID process-driven root causes of failure
810
2. Assess Risks
Conduct risk assessment (i.e. FMEA)
Medication usage process
805
1. Detect & Characterize Drug Risks
• liver toxicity
• bleeding
patient segmentation
805

Figure 9
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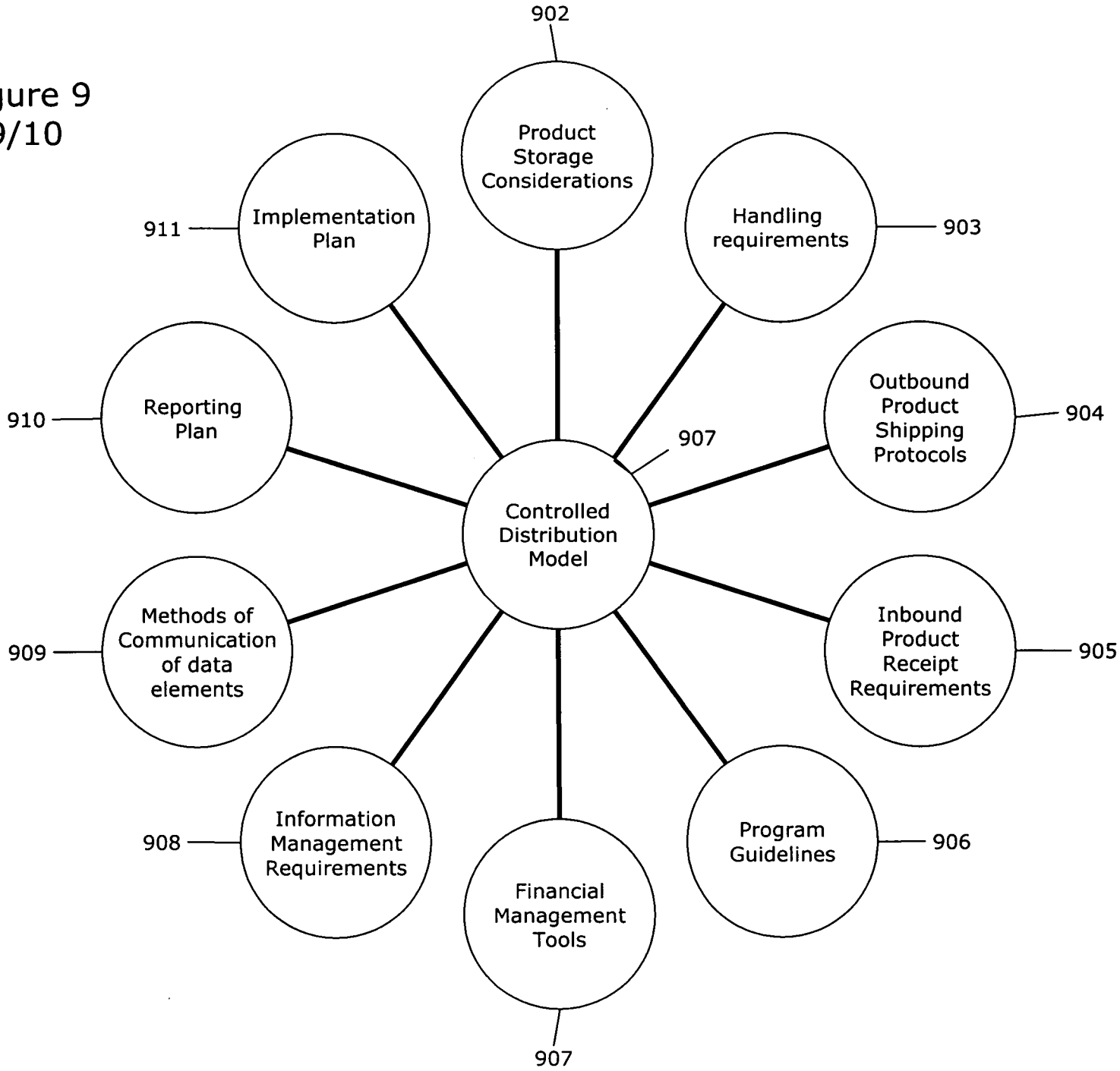
902
Product Storage Considerations
911
Implementation Plan
Handling requirements
903
910
Reporting Plan
Outbound Product Shipping Protocols
904
907
Controlled Distribution Model
909
Methods of Communication of data elements
Inbound Product Receipt Requirements
905
908
Information Management Requirements
Financial Management Tools
Program Guidelines
906
907
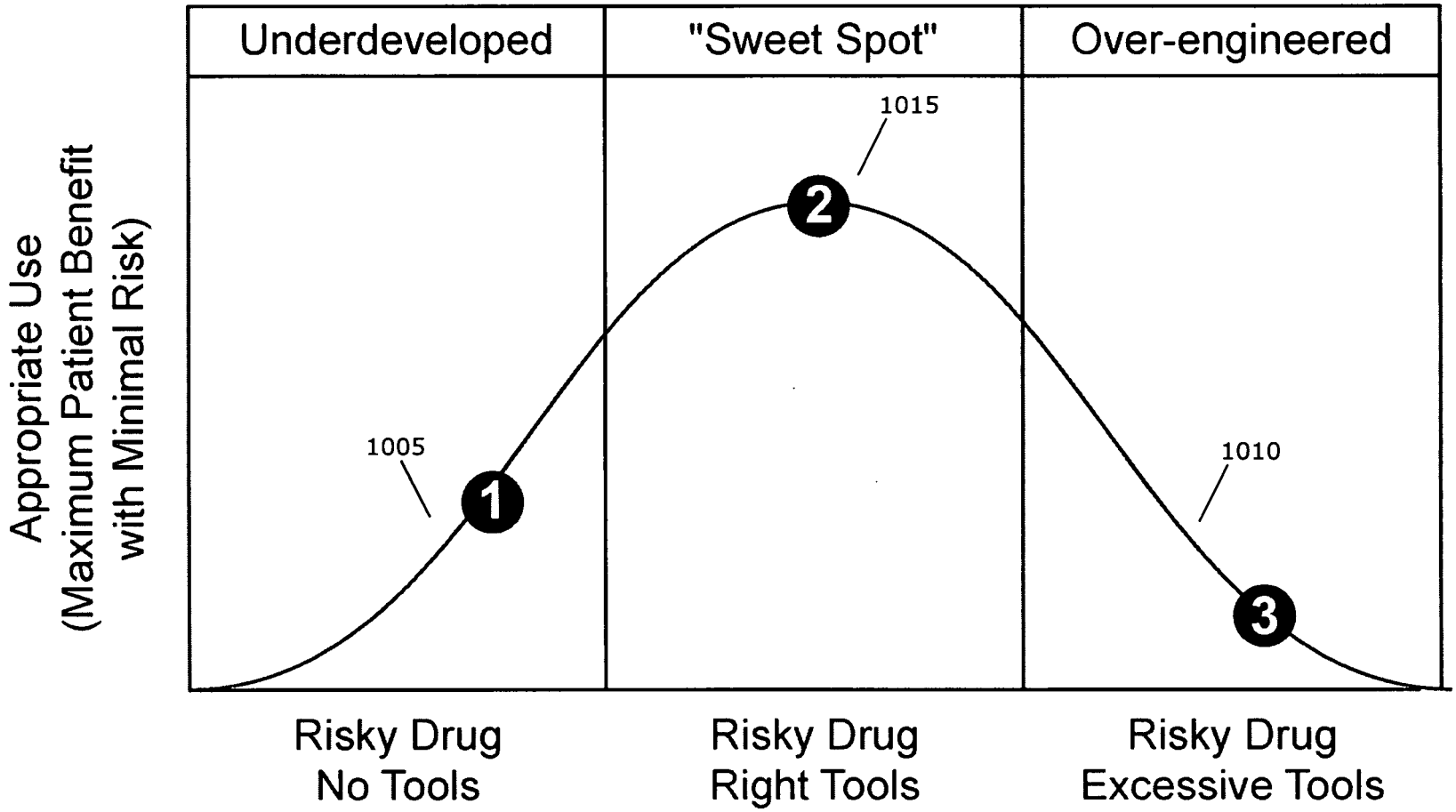
Figure 10
10/10